REMARKS:

In response to the Office Action mailed February 3, 2009, claims 94 and 97 have been canceled without prejudice, claims 91-93, 96, and 104-110 have been amended, and new claims 111-124 have been added. Accordingly, claims 91-93, 95, 96, and 98-124 are currently pending.

The amendments are fully supported by the original disclosure, for example, in the specification, e.g., between page 31, line 17 and page 32, line 4, between page 47, line 12 and page 49, line 1, and between page 65, line 22 and page 67, line 17, and in the drawings, e.g., in FIGS. 18 and 19. No new matter has been introduced.

In the Office Action, the drawings were objected to, the specification was objected to for informalities, and claim 93 was objected to for informalities. In addition, claims 91-103 were rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter, and claims 93, 96, 97, 103, and 110 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Finally, claims 91, 94, 98, 104, and 107 were rejected 35 U.S.C. § 102(b) as anticipated by German Publication No. DE 1992-114A1 ("the Fege reference"), claims 92, 95, 100, 105, and 109 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Fege reference, claims 93, 96, 97, and 106 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Fege reference in view of U.S. Publication No. 2003/ 0149445 ("the Knudson et al. reference"), and claims 99, 101-103, and 110 were also rejected under 35 U.S.C. § 103(a) as unpatentable over the Fege reference in view U.S. Publication No. 2002/ 0189727 ("the Peterson reference").

Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

As an initial matter, the originally filed drawings have been replaced with the enclosed formal drawings. In addition, the paragraphs on pages 4 and 5 of the specification have been amended to refer to the registered trademarks SOMNOPLASTY® and REPOSE®, as suggested by the Examiner.

With respect to the objection to the term "Nitinol," Applicants submit that this term is not a trademark, and, if it ever was a trademark, it has become generic for referring to nickel titanium alloys. For example, at Wikipedia, it is explained that "Nickel titanium (NiTi is a shape memory alloy also commonly referred to by the name, Nitinol. . . ." See http://en.wikipedia.org/wiki/Nickel_titanium. Thus, Applicants submit that the common usage of the term Nitinol in the present application would be understood by a person of ordinary skill to refer to nickel titanium alloys and not a specific trademark or product. Accordingly, Applicants request that this objection be withdrawn.

Turning to the objection to claim 93, a period has been added to the end of this claim, as suggested by the Examiner. Accordingly, Applicants submit that these objections have been overcome and should be withdrawn.

Turning to the § 101 rejections, Applicants submit that claim 91 does not recite part of the human body, but recites that the appliance is "***sized and structured*** to be placed in an oropharyngeal region of a human or animal with the central body portion extending generally laterally across the posterior wall and the end portions providing support to the lateral walls of the oropharyngeal region and, when so placed, being effective in treating at least one of sleep apnea and snoring." (emphasis added). With respect to claim 100, although Applicants believe that claim 100 also does not recite part of the human body, claim 100 has been amended to recite that

the appliance has a constrained configuration ***adapted*** for delivery into an oropharyngeal region, and an open configuration ***adapted for*** applying a radial force to the lateral walls when the appliance is so placed in the oropharyngeal region. Accordingly, Applicants submit that the § 101 rejections should be withdrawn.

With respect to the § 112, second paragraph, rejections, claim 92 has been amended to recite that the at least one element recited in claim 91 includes at least two elements, and claims 93 and 96 have been amended to more definitely refer to these at least two elements. Claim 97 has been canceled without prejudice for reasons unrelated to these rejections. In addition, claims 105 and 106 have been amended similarly to claims 92 and 93. Finally, as explained above, the term Nitinol would be understood by a person of ordinary skill to refer to nickel titanium alloys and not a specific trademark or product, and therefore the use of the term Nitinol in claims 103 and 110 should be definite. Accordingly, for these reasons, the § 112, second paragraph, rejections should be withdrawn.

Turning to the § 102(b) rejections, the Fege reference discloses a pair of implants 1 that include first ends 48, 54 secured to the spinal column 38 by screws, and second ends 50, 56 disposed against or implanted in the side edges of a tongue 4. As clearly shown in FIG. 1, the implants 1 are embedded directly through tissue between the spinal column 38 and the tongue 4, e.g., including through the masseter muscles 34. The implants 1 are not inserted into the oropharyngeal region, presumably the throat lumen 36 shown in FIG. 1.

Two additional implants 1' are also implanted that extend from the spinal column 38 up at a 45 degree angle up from the implants 1 above the tongue 4 and palate, as clearly shown in FIG. 2. Although the Fege reference makes a general statement that the implants 1 and 1' can become

single and combined with one another, there is absolutely no teaching how such a combined implant could be constructed, nor how such an implant could be introduced through tissue and anchored to the spinal column, as required by the Fege reference.

Turning to the present claims, claim 91 recites an apparatus for treating at least one of sleep apnea and snoring in a human or animal having an oropharyngeal region with lateral and posterior walls that includes an appliance including at least one element having a length extending from a first end to a second end and a relatively narrow, generally central body portion and terminating at relatively wide end portions adjacent the first and second ends, the appliance being sized and structured to be placed in an oropharyngeal region of a human or animal with the central body portion extending generally laterally across the posterior wall and the end portions providing support to the lateral walls of the oropharyngeal region and, when so placed, being effective in treating at least one of sleep apnea and snoring.

First, the Fege reference fails to disclose, teach, or suggest an appliance including at least one element having a length extending from a first end to a second end and a ***relatively narrow, generally central body portion*** and terminating at ***relatively wide end portions***, as claimed. Instead, at most, the Fege reference discloses implants 1, 1' that are merely uniform width strips, as shown in FIGS. 2 and 3. Further, even if relatively wide end portions were added to the Fege implants, the implants could not be introduced through tissue and anchored to the spinal column, because such wide end portions would interfere with introducing the ends through tissue to anchor the implants to the spinal column.

In addition, the Fege reference does not disclose, teach, or suggest an implant sized and structured to be placed ***in an oropharyngeal region*** of a human or animal with the central body

portion extending generally laterally across the posterior wall and the end portions providing support to the lateral walls of the oropharyngeal region. In contrast, as explained above, the Fege reference merely discloses implants that are implanted directly through tissue and not placed in an oropharyngeal region. One of the implants is anchored to the spinal column, and the other end extends into or above the tongue. Accordingly, for these reasons, claim 91 and its dependent claims are neither anticipated by nor otherwise obvious over the Fege reference.

For similar reasons, claims 111 and 116 are also not anticipated by or obvious over the Fege reference. Claim 116 also recites an appliance including at least one elongated element shaped to define a relatively narrow central body portion and relatively wide end portions adjacent first and second ends, the appliance adapted to be placed circumferentially around an oropharyngeal region of a human or animal such that the central body portion extends generally laterally across the posterior wall and the relatively wide end portions support the lateral walls of the oropharyngeal region.

Claim 111 also recites an appliance including two elongated elements coupled together at first and second ends, the elongated elements shaped to define a relatively narrow central body portion and relatively wide end portions adjacent the first and second ends, the appliance adapted to be placed circumferentially around an oropharyngeal region of a human or animal such that the central body portion extends generally laterally across the posterior wall and the relatively wide end portions support the lateral walls of the oropharyngeal region.

Turning to claim 104, a method is recited for treating at least one of sleep apnea and snoring in a human or an animal having an oropharyngeal region with lateral and posterior walls that includes providing an appliance including at least one element having a length extending from

a first end to a second end, the appliance comprising a central body portion between end portions adjacent the first and second ends; inserting the appliance into an oropharyngeal region in a constrained configuration; and releasing the appliance within the oropharyngeal region, thereby allowing the appliance to expand radially within the oropharyngeal region so that the central body portion extends generally laterally across the posterior wall and the end portions support the lateral walls of the oropharyngeal region.

First, as explained above, the Fege reference fails to disclose, teach, or suggest an appliance that is inserted into and released in an oropharyngeal region, but instead the Fege implants are implanted directly through tissue outside the oropharyngeal region. Further, the Fege reference does not teach or suggest inserting an appliance into an oropharyngeal region in a constrained configuration; and releasing the appliance within the oropharyngeal region, thereby allowing the appliance to expand radially within the oropharyngeal region. Accordingly, for these reasons, claim 104 and its dependent claims are also neither anticipated by nor otherwise obvious over the Fege reference.

Finally, for similar reasons to those given above, claim 119 and its dependent claims are also not anticipated by or otherwise obvious over the Fege reference. Claim 119 recites that the appliance includes at least one element having a length extending from a first end to a second end and a relatively narrow, generally central body portion and relatively wide end portions adjacent the first and second ends, which is wholly absent from the Fege reference, as explained above. In addition, the Fege reference fails to teach or suggest inserting an appliance into an oropharyngeal region, and releasing the appliance within the oropharyngeal region, thereby allowing the appliance to resiliently expand radially within the oropharyngeal region.

The remaining cited references do not provide any additional teaching or suggestion of the features wholly absent from the Fege reference. Therefore, even if the other references could be properly combined with the Fege reference (which Applicants do not concede), the present claims would not be obvious over the cited references.

In particular, the Knudson et al. reference discloses an expander member 20b that is completely incompatible with the Fege implants, particularly, as they disclose mutually exclusive approaches. The Fege reference discloses implants that are implanted into tissue extending from the spinal column to the tongue or above the palate, while the Knudson et al. reference discloses an expander member 20b including spacer bars 26b that extend across the pharyngeal airway and include wide compression members 24b for contacting the pharyngeal wall.

Further, the Knudson expander member 20b does not include at least one element having a length extending from a first end to a second end and a relatively narrow, generally central body portion and relatively wide end portions adjacent the first and second ends, as claimed, which is also missing from the teachings of the Fege reference. Finally, the Knudson expander member is incapable of being ***placed circumferentially around an oropharyngeal region*** of a human or animal such that the central body portion extends generally laterally across the posterior wall and the relatively wide end portions support the lateral walls of the oropharyngeal region. In direct contrast, rather than being placed circumferentially around an oropharyngeal region, the Knudson expander includes spacer bars that extend across and obstruct the oropharyngeal region.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Applicants hereby petition for any extension of time necessary to make the present response timely. Applicants believe that a three month extension is currently required.

Respectfully submitted,
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